K083609

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 6 2009

SUBMITTER INFORMATION

A.	Company Name:	KFx Medical, Corporation
B.	Company Address:	5845 Avenida Encinas Suite 128 Carlsbad, CA 92008
C.	Company Phone:	(760) 444-8844
D.	Company Facsimile:	(760) 602-9252
E.	Contact Person:	Gayle Hirota Quality Assurance & Regulatory Affairs Director

DEVICE IDENTIFICATION

A.	Trade Name:	KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle
B.	Catalog Number:	KFX-W-400F2 (4mm with 2 white sutures) KFX-B-400F2 (4mm with 2 blue sutures) KFX-WB-400F4 (4mm with 2 blue/2 white sutures) KFX-W-500F2 (5mm with 2 white sutures) KFX-B-500F2 (5mm with 2 blue sutures) KFX-WB-500F4 (5mm with 2 blue/2 white sutures) KFX-W-600F2 (6mm with 2 white sutures) KFX-B-600F2 (6mm with 2 blue sutures) KFX-WB-600F4 (6mm with 2 blue/2 white sutures)
C.	Common Name:	Bone Anchor
D.	Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
E.	Product Code:	MBI
F.	Device Class:	Class II (per 21 CFR 888.3040)

IDENTIFICATION OF PREDICATE DEVICES

The KFx PEEK Bone Anchor with Pre-attached Sutures and Delivery Handle is substantially equivalent to the existing KFx Knotless Fixation System, the Arthrex Corkscrew FT Suture Anchor, and the Opus Magnum Anchor with Inserter cleared by the Food and Drug Administration.

DEVICE DESCRIPTION

The KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle is intended for the fixation of soft tissue to bone using Teleflex ForceFiber™ #2 non-absorbable braided suture. The KFx PEEK Bone Anchor with Pre-Attached Sutures consists of a fixation device pre-loaded with suture in a delivery (insertion) handle. The PEEK bone anchor can be used in open or arthroscopic procedures.

INTENDED USE

The intended use of the KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle is for the fixation of soft tissue to bone in the shoulder, foot, ankle, knee, hand, wrist, and elbow. Please see indications for use statement for details.

TECHNOLOGICAL CHARACTERISTICS AND PERFORMANCE

The KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle is similar in materials, design, and operation to the predicate devices. Non-clinical test data has established that the devices satisfies functional performance requirements and is safe and effective when used as indicated.

BIOCOMPATIBILITY

The KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle is composed of materials that are currently utilized in a myriad of legally marketed orthopedic devices.

CONCLUSIONS DRAWN FROM STUDIES

The documentation provided in the 510(k) demonstrates that the KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle is substantially equivalent to the predicate devices and is safe and effective when used as indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2009

KFx Medical, Corporation
% Mr. Gayle Hirota
QA/RA Director
5845 Avenida Encinas, Suite 128
Carlsbad, California 92008

Re: K083609
Trade/Device Name: KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: December 5, 2008
Received: December 8, 2008

Dear Mr. Hirota:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3.2 Indications for Use

510(k) Number (if known): K083609

Device Name: KFx PEEK Bone Anchor with Pre-Attached Sutures and Delivery Handle

Indications For Use: The KFx Peek Bone Anchor with Pre-Attached Sutures and Delivery Handle is intended for the fixation of soft tissue to bone in the shoulder, foot/ankle, knee, hand/wrist, and elbow.

Specifically:

Shoulder: Bankart lesion repairs, SLAP lesion repairs, acromio-clavicular separation repairs, rotator cuff repairs, capsular shift or capsulolabral reconstructions, biceps tenodesis, deltoid repairs

Foot and Ankle: Hallux valgus repairs, medial or lateral instability repairs/reconstructions, Achilles repairs/reconstructions, mid-foot reconstructions, metatarsal ligament repair.

Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, Iliotibial band tenodesis, patellar tendon repair.

Hand/Wrist/Elbow: Scapholunate ligament reconstructions, ulnar or radial collateral ligament reconstructions, tennis elbow repair, biceps tendon reattachment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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